MAY 16 2012

510 (k) Summary of Safety and Effectiveness

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 112494

1. General Information:

Submitter:	Varaya Photoceuticals, LLC
Address:	16511 Scientific Way, Suite 200 Irvine, CA 92618 P: 949.753.1482 F: 949.753.1485 mykl@ldallc.com
Contact Person:	Frances Beckman, Owner C: 949.233.6156 fbeckman2@cox.net
Date Prepared:	March 19, 2012

2. Names:

Device Name:	Varaya Sport
Device Model No.:	200
Classification Name:	Lamp, Infrared
Common Name:	LED Light System
Review Panel:	Physical Medicine
Product Code:	ILY
Regulation No.:	890.5500

3. Predicate Devices:

Warp 10 (K032229), Tanda Pro Restore (K090008), Diomedics PainX 2000 Model 900 (K982546), RXLight (K100213).

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4. Device Description:

The Varaya Sport Model 200 utilizes high powered Light Emitting Diodes (LEDs) to distribute specific wavelengths of light energy. The LEDs are: one visible Red (660nm) and one invisible nearInfrared (850nm). The device is handheld .25" above the desired treatment area and operates when connected to an electrical outlet. The device has an on/off button and a control panel for a built-in timer and wavelengths. The device has integrated optics to ensure uniform distribution of light energy. The device comes with goggles for safety and a power cord/adapter.

5. Indications for Use:

For the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

6. Performance Data:

Based upon analysis, Varaya Photoceuticals, LLC believes there are no significant differences from the predicate devices.

7. Comparison to Predicate Devices:

The intended use and technological characteristics are similar or equivalent to the listed predicates.

8. Summary of Testing:

The Varaya Sport Model 200 meets the required tissue heating requirements (tests provided).

Formal clinical trials were not deemed necessary as device is using same or similar technology and intended use as predicate devices.

Information regarding testing safety and effectiveness in accordance with IEC 60601-1, IEC 60601-1-2 and ISO 10993 were provided.

9. Conclusion:

The Varaya Sport Model 200 meets the safety and efficacy requirements necessary for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 16 2012

Varaya Photoceuticals, LLC
% Myk Lum
16511 Scientific Way, Suite 200
Irvine, California 92618

Re: K112494
Trade/Device Name: Varaya AR, Varaya Sport
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: May 09, 2012
Received: May 14, 2012

Dear Myk Lum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) NUMBER: K112494

DEVICE NAME: Varaya Sport Model 200

INDICATIONS FOR USE:

The Varaya Sport Model 200 is indicated/intended for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Prescription Use: X and/or Over-the Counter Use: ___
(Part 21 CFR 801 Subpart D) (21CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112494